

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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ORTHO McNEIL PHARMACEUTICAL,		X	
INC., et al.,		X	
	Plaintiffs,	X	Civil Action No. 03-4678 (SRC)
		X	
	v.	X	OPINION
		X	
BARR LABORATORIES, INC.,		X	
		X	
	Defendant.	X	
<hr/>		X	

CHESLER, U.S.D.J.

This matter comes before the Court on two motions for partial summary judgment, pursuant to FED. R. CIV. P. 56. Plaintiffs Ortho-McNeil Pharmaceutical, Inc. and Johnson & Johnson Pharmaceutical Research & Development, LLC (collectively, “Ortho”) move for partial summary judgment on the affirmative defense of patent invalidity due to anticipation, pursuant to 35 U.S.C. § 102. Defendant Barr Laboratories, Inc. (“Barr”) moves for partial summary judgment on one aspect of the affirmative defense of patent invalidity due to obviousness, pursuant to 35 U.S.C. § 103. For the reasons stated below, both motions for summary judgment will be **DENIED**.

BACKGROUND

This is a patent infringement case brought under the Hatch-Waxman Act. On April 10, 2001, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 6,214,815 (the “’815 patent”). Ortho owns the ’815 patent. The claims of the ’815 patent cover the combination oral contraceptive that Ortho markets under the name “Ortho Tri-Cyclen Lo.”

In July of 2003, Barr filed an Abbreviated New Drug Application (“ANDA”), No. 76-784, with the United States Food and Drug Administration, seeking approval to market a generic version of Ortho Tri-Cyclen Lo prior to the expiration of the ’815 patent. On August 20, 2003, Barr notified Ortho of its certification that the ’815 patent is invalid due to anticipation and obviousness. On October 1, 2003, Ortho initiated the instant action by filing a Complaint for infringement of claims 1 and 4 of the ’815 patent. As affirmative defenses to patent infringement, Barr contends that these claims are invalid as anticipated and obvious in view of two prior art patents: U.S. Patent No. 4,616,006 (the “’006 patent”) and U.S. Patent No. 4,628,051 (the “’051 patent”).

Ortho moves for partial summary judgment on Barr’s affirmative defense of anticipation, contending that one of ordinary skill in the art could never have “at once envisaged” the claims at issue from either of the two prior art references, and that no reasonable factfinder could conclude otherwise. (Pls.’ § 102 Br. 3.)

Barr moves for partial summary judgment on one aspect of the affirmative defense of obviousness, the prima facie case. Barr contends that no factual disputes preclude judgment as a matter of law, and asks this Court to rule that the ’006 and ’051 patents render the claims at issue prima facie obvious. Barr does not move for partial summary judgment on the issue of obviousness as a whole, but only on the issue of prima facie obviousness.

LEGAL STANDARD

I. Summary Judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the

moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).¹

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for

¹ In patent cases, a district court applies its circuit's law of summary judgment. See CollegeNet Inc. v. ApplyYourself Inc., 418 F.3d 1225, 1230 (Fed. Cir. 2005).

summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). “[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment.” Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring nonmoving party to “set forth specific facts showing that there is a genuine issue for trial”). “A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial.” Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed “to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial, . . . there can be ‘no genuine issue of material fact,’ since a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

II. Patent Invalidity due to Anticipation

A patent may be invalidated for anticipation under 35 U.S.C. § 102, which states:

A person shall be entitled to a patent unless . . .

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

“A patent is presumed to be valid, 35 U.S.C. § 282, and this presumption can only be overcome by clear and convincing evidence to the contrary. A claim is anticipated if each and every

limitation is found either expressly or inherently in a single prior art reference.” Bristol-Myers Squibb Co. v. Ben Venue Labs., 246 F.3d 1368, 1374 (Fed. Cir. 2001) (citations omitted).

“Anticipation is a question of fact. However, without genuine factual disputes underlying the anticipation inquiry, the issue is ripe for judgment as a matter of law.” SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343 (Fed. Cir. 2005).

The party asserting invalidity bears the burden of establishing it. 35 U.S.C. § 282. “This burden is especially difficult when . . . the infringer attempts to rely on prior art that was before the patent examiner during prosecution.” Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004) (quotation omitted).

III. Patent Invalidity due to Obviousness

To patent an invention, the subject matter must be non-obvious:

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103(a).

“It is well-settled that obviousness is a legal question based on underlying factual determinations.” Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1323 (Fed. Cir. 2004) (quotation omitted).

[F]actual determinations relevant to the obviousness inquiry include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations, if any, such as commercial success, unexpected results, copying, long-felt but unresolved need, and the failure of others to develop the invention.

Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1378 (Fed. Cir. 2005).

“The concept of prima facie obviousness . . . is but a procedural mechanism to allocate in an orderly way the burdens of going forward and of persuasion as between the examiner and the applicant.” In re Piasecki, 745 F.2d 1468, 1471-1472 (Fed. Cir. 1984).

DISCUSSION

I. Plaintiff’s Motion for Partial Summary Judgment on Anticipation

Ortho moves for partial summary judgment on Barr’s affirmative defense of invalidity due to anticipation by the ’006 and ’051 patents. The parties do not dispute that, except for the estrogen dosage limitation, every limitation of claims 1 and 4 of the ’815 patent is found expressly in the specification of both of the prior art patents. Example 4 in both the ’006 and ’051 patents contains the 7/7/7 regimen with the same progestogen dosages and phasing as appears in claims 1 and 4 of the ’815 patent. Although Example 4 does not describe the use of 7 dosage units free of estrogen and progestogen, those limitations are found in the specification of both patents (e.g., ’006 Patent, col. 3 ll. 42-49.) There is no dispute that the only limitation in claims 1 and 4 of the ’815 patent *not* in the prior art Example 4 (read in conjunction with the remainder of the specification) is the 25 microgram dose of ethinyl estradiol (“EE”) (since Example 4 discloses a 35 microgram dose of EE). (Pls.’ § 102 Br. 13; Def.’s § 102 Opp. Br. 4.)

The prior art patents do, however, disclose “contraceptively effective dosages corresponding in activity to 0.02 - 0.05 mg of” EE.² (’006 Patent, col. 8 ll. 9-11; ’051 Patent, col. 7 ll. 21-23). The core of the dispute over anticipation is the question of whether the prior art disclosure of the range of 20 to 50 micrograms of EE describes the 25 microgram EE dosage limitation, within the meaning of 35 U.S.C. § 102.

² This is equal to a range of 20 - 50 micrograms of EE.

There is no substantial dispute over the relevant legal standard, although each party phrases it differently. Ortho phrases the question as whether one of ordinary skill in the art would have “at once envisaged” the 25 microgram dosage after having reviewed the prior art, while Barr states the question as whether the prior art described the 25 microgram dosage to one of ordinary skill in the art, such that it would have been “immediately apparent.” (Pls.’ § 102 Br. 2; Def.’s § 102 Opp. Br. 22-23.) Ortho states that the “immediately apparent” formulation does not differ from the “at once envisaged” standard. (Pls.’ § 102 Reply Br. 6 n.5.) Barr does not contend that the differences in phrasing have any legal significance for the purposes of this motion. Each wording attempts to express the § 102(b) requirement that the invention be “described.”

Ortho argues that the prior art references encompass millions and billions of possible regimens – an amount so large that one of ordinary skill in the art could never have “at once envisaged” every one of them. Ortho contends that summary judgment is appropriate because “[n]o factfinder could reasonably conclude otherwise.” (Pls.’ § 102 Br. 23.) Barr responds by pointing to the expert report and deposition testimony of Dr. Simon. Dr. Simon’s expert report and deposition testimony express Dr. Simon’s expert opinion that the ’006 and ’051 patents describe a regimen with a dosage of 25 micrograms of EE to one of ordinary skill in the art, such that this would have been apparent upon review of these prior art references. (Kaplan Decl. Ex. 8 471:21 - 475:2; Simon Decl. Ex. 1 ¶¶ 24, 34.)

Ortho makes a number of legal arguments in response, but does not address the crucial question of whether Barr, in offering Dr. Simon’s report and testimony, has established the existence of a genuine issue as to a material fact for trial. The question of whether, pursuant to

35 U.S.C. § 102(b), the prior art reference described the invention to one of ordinary skill in the art is an issue of fact, and Barr has “set forth specific facts showing that there is a genuine issue for trial.” FED. R. CIV. P. 56(e). A reasonable jury could hear the evidence offered by Barr and find in favor of Barr at trial. Ortho has not argued to the contrary.

Ortho attempts to avoid the factual dispute by arguing that the Petering principle that a genus may anticipate a species “applies only where the application of preferences set forth in the prior art yields a limited class of species.” (Pls.’ § 102 Reply Br. 7.) This misreads Petering. In that case, the C.C.P.A. found that the preferences stated in the prior art patent, read in combination with the generic formula, constituted sufficient description to anticipate. In re Petering, 301 F.2d 676, 681 (C.C.P.A. 1962). The Petering court did not hold that *only* the application of preferences could enable a genus to anticipate a species. Rather, the Petering Court required only that the prior art patent “describe[]” a limited class such that one of ordinary skill in the art would “at once envisage each member of this limited class.” Id. Thus, Petering does not require the use of preferences to describe a limited class, but only that the prior art somehow describe a limited class such that one would at once envisage every member.³

Ortho argues as well that Barr’s position entails “picking and choosing snippets” of disclosures in the prior art, which the C.C.P.A. stated was impermissible in In re Arkley, 455 F.2d 586, 587 (C.C.P.A. 1972). (Pls.’ § 102 Reply Br. 10.) This argument is itself an example of choosing a snippet: reading the entire sentence, the Arkley Court held that picking and choosing was impermissible when the “various disclosures [are] not directly related to each

³ The Court notes that, in Ortho’s moving brief, preferences were merely “a factor considered important” in Petering. (Pls.’ § 102 Br. 22.) In Ortho’s reply brief, “important” grew to “limiting.”

other by the teachings of the cited reference.” In re Arkley, 455 F.2d at 587. Ortho’s Arkley snippet, when read in context of the complete sentence in which it appeared, invokes an argument that rests on an analysis that Ortho has not done. Crucially, Ortho does not argue that the 25 microgram EE dosage and, for example, the 7/7/7 regimen are disclosures that are not directly related to each other by the teachings of the cited references.

Ortho also argues that the Court, in making the summary judgment determination, must consider Barr’s heavy burden of proving invalidity based on prior art that was before the examiner. This is correct. Yet it is also true that, at summary judgment, this Court must believe the evidence offered by the nonmovant. Anderson, 477 U.S. at 255. A factfinder believing Barr’s evidence might reasonably find that the heavy burden of proof has been met.

Barr has offered evidence sufficient to show the existence of a genuine issue as to a material fact for trial and thus has defeated Ortho’s motion for partial summary judgment on anticipation. Ortho’s motion for partial summary judgment on anticipation will be denied.

II. Defendant’s Motion for Partial Summary Judgment on Prima Facie Obviousness

Barr asks this Court to enter partial summary judgment that the ’006 and ’051 patents render claims 1 and 4 of the ’815 patent prima facie obvious. Barr contends that the prosecution history of the ’815 patent shows that the PTO consistently maintained that these claims were prima facie obvious in view of the prior art patents, and asks this Court to enter summary judgment in accord with the PTO’s position. This would dispose of the issue of prima facie obviousness, and the obviousness determination as a whole would be completed at trial.

In opposition, Ortho argues that this motion is procedurally improper, and that entry of summary judgment on this issue at this point in the case would not facilitate resolution of the

obviousness question but, rather, would hamper the analysis of the issue at trial. This position has merit.

The predecessor Court to the Federal Circuit explained the concept of prima facie obviousness in In re Rinehart, 531 F.2d 1048, 1052 (C.C.P.A. 1976):

The concept of rebuttable prima facie obviousness is well established. It is not, however, a segmented concept. When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over. Though the burden of going forward to rebut the prima facie case remains with the applicant, the question of whether that burden has been successfully carried requires that the entire path to decision be retraced. An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only on its knockdown ability. Analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect. Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record.

Id (citations omitted). Rinehart is still good law. See In re Kumar, 418 F.3d 1361, 1366 (Fed. Cir. 2005) (citing Rinehart).

In the language of Rinehart, Barr asks this Court to segment the concept of obviousness, and this is improper. If the Court were to agree with Barr, and were to enter partial summary judgment on the prima facie case, there are two possible consequences, both undesirable. The decision could be treated at trial as "set in concrete," which Rinehart warns would be a mistake. In the alternative, this Court could follow the guidance of Rinehart and, at trial, retrace the entire path to decision, in which case the work done to decide this motion would have to be repeated. There is simply no benefit to doing an analysis now which will have to be done again at trial. In

fact, as Rinehart states, to do so is to risk creating for prima facie obviousness an undeserved significance, since the eventual obviousness determination must be uninfluenced by earlier conclusions. Barr's motion for partial summary judgment on prima facie obviousness will be denied.

CONCLUSION

For the reasons stated above, as to Ortho's motion for partial summary judgment on Barr's affirmative defense of anticipation, Barr has demonstrated that a genuine issue of material fact precludes summary judgment. Ortho's motion for partial summary judgment on Barr's affirmative defense of anticipation is denied. As to Barr's motion for partial summary judgment on one aspect of the affirmative defense of obviousness, the prima facie case, Barr has failed to persuade this Court that it is entitled to judgment as a matter of law. Barr's motion for partial summary judgment on the prima facie case is denied.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: October 23, 2006